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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/986,725	11/09/2001	Bo Skaaning Jensen	2815-0183P	5880

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BIRCH STEWART KOLASCH & BIRCH  
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EXAMINER
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FORD, JOHN M

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 01/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

09/986,725

**Applicant(s)**

JENSEN ET AL.

**Examiner**

John M Ford

**Art Unit**

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on Dec 31, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1, 1A, 20, 21, 31 and 34 is/are pending in the application.
- 4a) Of the above claim(s) 20, 21 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 1A and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

Applicants changed the claims in <sup>a</sup>supplementant <sup>and</sup>~~apply~~ of Dec. 31, 2003.

The claims now present for examination are claims 1, 18 and 34.

Claims 20, 21 and 31 stand withdrawn, as they are not of the same scope, as claim 1, as they call for an additional active ingredient.

Claim 1 is rejected, as a method for inhibiting T cell proliferation does not meet the Utility guidelines, as being directed to a specific, real World disease.

A IK ca modulating activity, likewise, does not recite a real world disease.

Therefore, claim 1 is rejected under 35 USC 112, 1<sup>st</sup> paragraph.

The recent guidelines set by PTO require applicants to meet the requirements as stated Brenner b. Manson in, 148 USPQ 689, which requires that utility be developed to a point where "specific benefits exist in currently available form". Similar is the "immediate benefit to the public" standard that Nelson v. Bowler, 206 USPQ 880 refers to. The standard set forth in the concurring opinion of In re Hartop, 135 USPQ 419 is "whether the invention has been brought to such perfection as to be capable of practice employment". This language is echoed in Bindra vs. Kelly, 206 USPQ 570.

The PTO has amended the guidelines to clarify "specific utility". The Court focused on the fact that the applicant failed to identify a "specific utility" in Brenner v. Manson, above.

The requirement of one specific utility is consistent with Unity of Invention Practice in International Applications and National Phase Applications under 35 USC 371, and PCT Rule 13.2 for PCT applications.

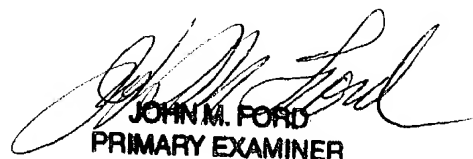
Therefore, applicants should limit the method claims to a "specific utility".

The Board of Appeals and the CCPA have held that the patent Office is not precluded from finding an inference of human use and require proof when such use is a medical nature for the treatment of a serious disease, such as cancer; Ex parte Moore et al., (POBA 1960) 128 USPQ 8; In re Citron. (CCPA et al.) 325 F2d 248, 139 USPQ 516 ; In parte Hartop et al., (CCPA 1962) 311 F2d 249, 135 USPQ 419.

The Supreme Court declined to express a view as to whether patentability can be based on a product shown to inhibit the growth of tumors in laboratory animals. Brenner, Comr. Pats. Vs. Manson, (USSC 1966) 383 U.S. 519, 148 USPQ 689. The Court did state, however, that Congress did not intend that a patent be granted on a chemical compound, or a process for its production, whose sole "utility: consists of its potential role as an object of use-testing, reasoning the patent system is related to the ~~W~~orld of ~~C~~ommerce rather than the realm of philosophy ibid., 148 USPQ at 696.

The U.S.P.T.O has amended guideline to clarify "specific utility.". The focus was on Brenner v. Manson. The utility need be one in the real World of Commerce.

The utility of a process for producing remissions in patients suffering from chronic myeloid leukemia was established by clinical reports and data, the acceptance of the drug employed by the Food and Drug Administration and by the American Medical Association Council on Pharmacy, were alleged in the specification. Ex parte Timmis, (POBA 1959) 123 USPQ 581. Evidence involving a single compound and two types of cancer, was held insufficient to establish the utility of claims directed to a method of treating seven types of cancer with a member of a class of several compounds. In re Buting, (CCPA 1969) 418 F2d 540, 163 USPQ 689.

  
JOHN M. FORD  
PRIMARY EXAMINER  
